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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,220	05/17/2005	Juan Carlos Domingo Pedrol	OFI001-823324	9405

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,220	DOMINGO PEDROL ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-14 have been cancelled and Claims 15-28 have been added by the Applicant in correspondence filed on 11/14/2008. Claims 15-28 are currently pending. This is the second Office Action on the merits of the claim(s).

Priority

2. Applicant's claim for the benefit of a prior-filed international application PCT/IB03/05673 (filed on 12/01/2003) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Examiner was in error when granting the benefit of the international application in office action mailed on 08/14/2008. The effective filing date of the instant application is 05/17/2005. This is because Applicant has not properly claimed the benefit of the international application. Once Applicant has properly claimed the benefit of the international application (e.g. amending the specification or submitting an Application Data Sheet to claim the benefit), the effective filing date will be that of the international application.

3. If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The foreign priority document P-200202963 does not establish an effective filing date; rather it establishes the right of foreign priority. Since Applicant has not properly claimed the benefit of the international application, Applicant is also denied priority to the Spanish patent application because it was filed more than 12 months prior to the filing date of the instant application, PCT/IB03/05673. If Applicant properly claims the benefit of the international application, the priority date of the instant application would be 12/05/2002.

Response to Arguments

6. Applicant's response filed on 11/14/2008 to the Non-Final rejection mailed out on 08/14/2008 is acknowledged herewith.

7. In view of applicants cancellation of Claims 1-14 the 35 U.S.C. § 112 2nd paragraph rejection of Claims 1-14 and the 35 U.S.C. § 101 rejection of Claims 1-14 are herein withdrawn. Newly added claims 15-28 are examined on their merits and the following **FINAL** rejection is made.

Claim Rejections - 35 USC § 112 (2nd paragraph)

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23 and 24 recite the limitation that DHA is present in a concentration of between 5% and 100% or 50% and 100%, respectively, by weight. These claims imply that DHA is a part of a composition when it accounts for less than 100% by weight. Claims 23 and 24 depend, ultimately, on Claim 15, in which there is no limitation of the DHA as part of a composition. Therefore, Claims 23 and 24 lack antecedent basis of DHA as part of a composition.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 15-22, and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretty and Babish (US PreGrant Publication No. 2004/0106591, which claims the benefit of provisional application 60/428,246, filed on 11/22/2002).

12. Claim 15 of the instant application is drawn to a method of treating lipodystrophy in a patient receiving HAART comprising administration of DHA. Claims 16 and 17 limit the daily dose of DHA to 100 mg/day or 4 g/day, respectively. Claims 18-22 limit the method to an intended result of the DHA. Claims 25 and 26 limit the route of administration to oral or

parenteral, respectively. Claim 27 limits the patient to a human. Claim 28 limits the human to one infected with the HIV virus.

13. Pacioretty and Babish teach a method of treating fat maldistrubtion (e.g. lipodystrophy) in an HIV-infected human patient receiving anti-retroviral therapy (ART) comprising a conjugated fatty acid, such as docosahexaenoic acid (DHA) (paragraph 0059, Claims 21 and 22). The preferred daily dose ranges from 0.05 g (e.g. 50 mg) to 20 g of conjugated fatty acids (i.e. DHA) per day (paragraph 0062). ART is defined to include all therapies used to affect HIV-1 retrovirus replication, such as reverse transcriptase and protease inhibitors. HAART utilizes both reverse transcriptase inhibitors and protease inhibitors. The route of administration of the fatty acid can be oral or parenteral (paragraph 0079, lines 5-6). Claims 18-22 limit the method to an intended result (i.e. the DHA has a hypolimemiant activity). Such "wherein" clauses are not considered to be material to patentability, as it is assumed that the ability of DHA to possess, for example, a hypolipemiant activity is inherent in the compound. "A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005) (MPEP § 2111.04). Therefore, Pacioretty and Babish anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacioretty and Babish (above).

17. Claim 1 was described above. Claims 23 and 24 limit the concentration of DHA by weight percentage to range between 5% and 100%, or between 50% and 100%, respectively.

18. Pacioretty and Babish teach a method of treating lipodystrophy in patients receiving HAART comprising administration of DHA. Pacioretty and Babish do not disclose a specific weight percentage of DHA in the administrated compound.

19. Pacioretty and Babish disclose numerous compositions comprising linoleic acid in weight percentages of about 50% and above (Examples 1, 2, 3, 6, 7, and 8). DHA has more carbons (22) than linoleic acid (18), and a higher degree of unsaturation. Despite these differences, DHA and linoleic acid are structurally similar, and can be used for similar purposes (i.e. to treat lipodystrophy), such that one of ordinary skill in the art would be motivated to replace linoleic acid with DHA in the compositions taught by Pacioretty and Babish. Therefore, it would have

been *prima facie* obvious to modify the compositions of the prior art to replace linoleic acid with DHA.

20. Claims 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001) in view of and Connor, et al. (Annals of the New York Academy of Sciences, 1993).

21. Claims 15-28 are described above.

22. Holstein, et al., teach that HAART treatment causes lipodystrophy and hyperlipidemia (abstract). Lipodystrophy is defined by Stedman's Medical Dictionary as defective metabolism of fat, such that there is a dearth of subcutaneous fat. As such, hyperlipidemia can be interpreted to be a form of lipodystrophy, and treating hyperlipidemia is tantamount to treating lipodystrophy. Holdstein, et al., do not teach a method of treating lipodystrophy with DHA.

23. Connor, et al., teach that n-3 fatty acids (i.e. DHA) from fish oil has "profound hypolipidemic effcts" in hypertriglyceridemic patients with hyperlipidemia (abstract). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a composition known to treat lipodystrophy (DHA) as a therapy for lipodystrophy, which is a known complication of HAART in HIV-infected patients.

24. Neither Holstein, et al., nor Connor, et al., disclose specific dosages of DHA or a weight percentage of DHA. Such determinations would be considered routine optimization, which is not a patentably distinguishing limitation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP § 2144.05(II)(A)). Claims 18-22 limit the method to an intended result (i.e. the DHA has

a hypolimemiant activity), which is not a patentably distinguishing feature (see above 35 U.S.C. §102 rejection).

Conclusion

25. No claims are allowed.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

27. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625